

**Peter MacCallum Cancer Centre**

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## Patient Information and Consent Form

<b>Title</b>	Managing Cancer and Living Meaningfully (CALM) in people with non-small cell lung cancer treated with novel therapies: A pilot study
<b>Principal Investigator</b>	Dr Fiona Lynch
<b>Protocol Version</b>	V5, 29 <sup>th</sup> November 2022
<b>Ethics Approval Number</b>	21/245

This Patient Information and Consent Form is 5 pages long. Please make sure you have all the pages.

### 1 Introduction

You are invited to take part in this project, which aims to deliver and assess a psychological therapy called Managing Cancer and Living Meaningfully (CALM) with people with advanced lung cancer who have received immunotherapies or targeted therapies at Peter MacCallum Cancer Centre.

This form explains the project and what you will do if you decide to take part. Please read this information carefully. Please ask questions about anything you do not understand or want to know.

Your participation in this project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision to take part or not to take part in this project, or to take part and then withdraw, will not affect your care or your relationship with your treating staff. If you do not want to take part, but later change your mind, please contact the project team.

If you decide you want to take part in this project, you will be asked to sign the consent section of this form. You will be given a copy of this form to keep.

### 2 What is the purpose of this project?

The purpose of this research is to understand the usefulness of the CALM therapy for people with advanced lung cancer who have been treated with novel therapies. CALM has been developed for people with advanced cancer but has not yet been assessed with people treated with novel therapies. We aim to get feedback from patients about their experience with the therapy.

This project is led by Dr Fiona Lynch, Clinical Psychologist at Peter Mac. The project is funded by a Peter Mac Cancer Foundation Grant.

### 3 What will I need to do if I am involved in this project?

If you choose to take part in this project, you will complete initial screening questions to check your eligibility. If you it is suitable for you to participate, you will be referred to a CALM therapist who is a Peter Mac clinician with specialised training in this therapy (e.g., a clinical psychologist or nurse consultant). You will be provided with three to six individual CALM therapy sessions with your clinician aimed to help how you are feeling about your lung cancer. These sessions will be held across approximately six months or less. You can have these sessions as often as you would like them, usually fortnightly for the first few sessions. These sessions can be delivered in person at Peter Mac, or over telehealth (video call). Occasionally you and your therapist might decide you need a phone appointment if suitable. If you have a support person such as a partner, family member, or caring friend, you can invite them to attend some sessions with you if you would like this.

If you are not suitable to participate after screening, you will be offered a referral to our usual Peter Mac clinical psychology team.

**Questionnaires:** You will be asked to complete a set of three questionnaires about your quality of life, mood, and your thoughts and feelings about the possibility of death and dying. These questionnaires will take approximately 10 minutes. You will complete these before the start of your therapy, at completion of therapy, and again after three and six months. You may choose to complete these in person, return a hardcopy by mail using a supplied reply-paid envelope, or online through a secure survey. Your responses to these three questionnaires will be shared with your CALM therapist whilst you are working with them. After completing the therapy, you will also be asked to complete a once-off short questionnaire on your experience of the CALM therapy and of your therapist. If the questionnaires are not returned within two weeks, we will send you a reminder either by text, email, or by phone.

**Interviews:** After you complete your CALM therapy, you will be invited to take part in an interview about your experience of the CALM therapy. This interview will be completed over the phone, over telehealth (video-call) or in person if you prefer. This interview will last for approximately 30-45 minutes and be conducted by a member of the research team. This interview will be audio recorded and transcribed for analysis. You can decline to take part in this aspect of the study by ticking 'No' to the corresponding question on the consent form below. This will not affect your participation in the rest of the study.

**Other information:** We are also asking for your permission and consent to use information from your medical record. This information includes your age and gender (these are your demographic data), your contact details, and the treatment you are receiving or have previously received.

Your CALM sessions will be audio recorded so that we can assess that the intervention was delivered appropriately. Each audio recording will be assigned a unique identifier. The audio files will be stored in a secure location and will only be accessible by the study investigators. All files will be deleted five years after publication or dissemination of project outcomes, whichever is later. A small selection of audio recordings will be reviewed by the CALM supervisor during group supervision involving the Peter Mac CALM therapists.

If you wish to decline consent to have the sessions recorded, please tick 'No' on the consent form below or advise your therapist at the time. You can consent now to the recordings, and change your mind at any time. If you decline recordings, it will have no impact on treatment and you will be able to continue participation in the study and CALM therapy.

There are no costs associated with participating in this research project, nor will you be paid.

Should you wish to receive the overall results of this project you should inform the project team at the time of providing consent. We will send you these results at the end of the project.

### 4 What are the possible benefits of taking part?

There are no direct benefits for participating and you will not be reimbursed. However, during this study you will receive the CALM therapy that has been previously shown to be helpful for other people with advanced

cancer. You will also be contributing to improve understanding of whether the CALM therapy is useful for people who have been treated with immunotherapy or targeted therapy.

## **5 What are the possible risks or disadvantages of taking part?**

There are no physical risks associated with this project. It is possible that you may become distressed when answering the questions or when receiving the treatment during this project. If you experience distress during a treatment session your therapist will be there to support you. If you feel distressed outside a treatment session, please feel free to contact one of the project team members who will be able to help you find appropriate support. Alternatively, you can contact Cancer Council on **13 11 20** for telephone support. It is also possible that the treatments trialled here will have no effect on how you are feeling.

## **6 What if I withdraw from this project?**

If you do consent to participate, you may withdraw at any time up until the completion of the project. If you decide to withdraw from the project, please notify a member of the research team or your therapist.

You should be aware that data collected up to the time you withdraw will form part of the overall project results. If you do not want your data to be included, you must tell the project team member when you withdraw from the project, you will be able to withdraw all data except your basic details including treatment, sex, age, marital status, highest level of education completed and reasons for withdrawing. After completion of the project, your data will be included in the overall results and you will no longer be able to withdraw your data.

## **7 What will happen to information about me?**

By signing the consent form, you consent to the project team collecting and using personal and health information about you for the evaluation of this project. We will keep this data in an unidentifiable format after the completion of the project to protect your privacy. The data will be stored on password protected computer files which will only be accessed by the project team.

Data will be stored for a period of seven (7) years and then will be confidentially destroyed.

Each time we see, call, or contact you, we will make a short note on your medical file at Peter Mac including a brief summary of your session so that your treating team are aware that we have seen or contacted you. This note is also visible in your file at the Royal Melbourne Hospital or Royal Women's Hospital if applicable. Please also note that we have a duty to ensure the safety of each participant, and so if you provide us with information that makes us very concerned about your safety or someone else's safety, we will let your medical team or your support person know. When your therapist discusses your therapy at a group supervision session with CALM supervisor Dr Gary Rodin, they will also write a more detailed note summarising your session to be sent to Dr Gary Rodin and stored in password protected research file.

The results of this project may be published or presented at seminars and conferences, but it will be done in a way that cannot identify you. Some journals will keep the overall de-identified data for an indefinite period.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the project team. You have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

## **8 Who has reviewed the project?**

All research in Australia involving people is reviewed by an independent group of people that form a Human Research Ethics Committee (HREC). The ethical aspects of this project have been approved by the HREC of the Peter MacCallum Cancer Centre.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human intervention (research and non-research) studies.

## 9 Further information and who to contact

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project (for example, feelings of distress), you can contact the Project Lead Fiona Lynch on 8559 8236 or any of the following people:

Project contact person	Peter Mac complaints person	Peter Mac Ethics Committee
Fiona Lynch	Position Consumer Liaison	Peter Mac Ethics Coordinator
Telephone: (03) 8559 8236	Telephone: (03) 8559 7517	Telephone: (03) 8559 7540
Email: <a href="mailto:fiona.lynch@petermac.org">fiona.lynch@petermac.org</a>	Email: <a href="mailto:consumerliaison@petermac.org">consumerliaison@petermac.org</a>	Email: <a href="mailto:ethics@petermac.org">ethics@petermac.org</a>

## Consent Form

Title	Managing Cancer and Living Meaningfully (CALM) in people with non-small cell lung cancer treated with novel therapies: A pilot study
Project and Ethics Approval Number	
Project Sponsor	Peter MacCallum Cancer Centre
Principal Investigator	Dr Fiona Lynch

### Declaration by patient

- I have read the Patient Information and Consent Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the project.
- I have had an opportunity to ask questions about the project and what is required of me, and I am satisfied with the answers I have received.
- I freely agree to participate in this project as described and understand that I am free to withdraw at any time during the project without affecting my future care.
- I understand that I will be given a signed copy of this document to keep.

In relation to this project, please tick your response to following:

**I give my consent to be audio recorded during the therapy sessions** (to ensure the program is being delivered as intended)

☐ Yes ☐ No

**I give my consent to be invited to participate in interviews about my experience of the therapy that will be audio recorded**

☐ Yes ☐ No

Name of Patient (please print) _____	
Phone number: _____	Email: _____
Signature _____	Date: _____

### Declaration by staff member consenting the patient to the project<sup>†</sup>

I have given a verbal explanation of the project, its procedures and risks. I believe that the patient has understood that explanation.

Name <sup>†</sup> (please print) _____	
Signature _____	Date: _____

<sup>†</sup> An appropriately qualified member of the project team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.